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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,338	11/13/2000	Alexander Blinkovsky	4990.210-US	8547

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NOVOZYMES BIOTECH, INC.
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EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/712,338	Applicant(s) BLINKOVSKY ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-45 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,35,36,38-40,42-45 and 50-54 is/are rejected.
- 7) ☒ Claim(s) 32-34,37,41, and 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response of May 18, 2004 to the First Action on the Merits of this case is acknowledged. It is acknowledged that applicants have cancelled Claims 46-49, amended Claims 30, 31, 34, 38, and 39, and added new Claims 50-55. Claims 30-45 and 50-55 are pending and are hereby considered.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 30, 31, 36, 38, 40, 42-45 under 35 U.S.C. 112, first paragraph, for lack of enablement, as described in the prior action, is maintained. New Claims 50, 51, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. That, the first paragraph of section 112 requires nothing more than objective enablement; how such a teaching is set forth is of no importance. That, the fact that the specification does not establish the regions of protein structure which may be modified without effecting carboxypeptidase activity and the general tolerance of the carboxypeptidase activity to modification of the protein structure is not sufficient to render the claims non-enabled. The claimed sequences are structurally similar, having at least 80% identity. That, Applicants have provided methods for isolating the claimed nucleic acid molecules and determining if the

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encoded proteins have carboxypeptidase activity. That, companies which develop enzymes are able to produce and screen thousands of enzymes in a short period of time using robotics.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that the art teaches how to make variant polynucleotides and how to test a polypeptide for carboxypeptidase activity. It is also acknowledged that robotics enhance the speed at which enzymes can be produced and assayed for activity. However, the vast majority of the polypeptides encompassed by the scope of the current claims will not have carboxypeptidase activity. The specification fails to provide any guidance for the selection of which of the infinite number of variants have the claimed activity. Without such guidance, one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification. Therefore, rejection is maintained.

Written Description

Claims 30, 31, 35, 38, 39, 40, 42-45, and 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose polynucleotides (i) encoding residues 19-555 of SEQ ID NO: 2 (ii) encoding a polypeptide having 80%, 85%, 90%

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or 95% identity with residues 19-555 of SEQ ID NO: 2, (iii) that hybridize with residues 55-1662 of SEQ ID NO: 1, or (iv) encoding a polypeptide having 85% identity with SEQ ID NO: 2. As such, 30, 31, 35, 38, 39, 40, and 50-53 introduce New Matter and are, thus, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the Written Description requirement. Claims 42-45, in reciting vectors and host cells comprising the polynucleotide of Claim 30, as well as methods for making the encoded polypeptide, are rejected for the same reasons.

Allowable Subject Matter

Claims 33, 34, 37, 41, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

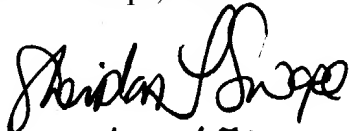
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.


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